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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,050	06/20/2001	Liat Mintz	2786-0177P	2695

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EXAMINER

JIANG, DONG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 01/02/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/884,050

Applicant(s)

MINTZ ET AL.

Examiner

Dong Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 6-13, 17, and 20-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 14-16, 18 and 19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6/20/01 6) ☐ Other:

**DETAILED OFFICE ACTION**

Applicant's election with traverse of Group I invention, claims 1-5, 14-16, 18 and 19, in Paper No. 10, filed on 21 October 2002 is acknowledged. The traversal is on the ground(s) that it is improper in that it deems unitary compositions and methods for use thereof to be separate inventions, and that the Examiner has not shown independence of the claims of groups II and III from the claims of group I. This is not found persuasive because, according to MPEP 803, an application may properly be required to be restricted if they are able to support separate patents and they are *either* independent *or* distinct, and group I and group II inventions are patentally *distinct* inventions for the reasons addressed in the last Office Action, paper No. 9, page 2.

The requirement is still deemed proper and is therefore made FINAL.

Applicants traversal on the restriction requirement between other groups not involving group I is moot as they are drawn to non-elected inventions.

Currently, claims 1-30 are pending, and claims 1-5, 14-16, 18 and 19 are under consideration. Claims 6-13, 17 and 20-30 are withdrawn from further consideration as being drawn to a non-elected invention.

The reference listed on the PTO-1449 filed on 20 June 2001 is not present in the current application file. In response to this Office Action only, applicants may submit another copy of the same reference, and the Examiner will consider it as though it were submitted with IDS filed on 20 June 2001.

**Request for Rejoinder:**

Applicants indicate that it is the correct practice to include in a single application claims directed to a composition and either method of use or method of production claims limited to allowable scope of the corresponding composition is noted. However, as no claims have been indicated to be allowable, this request will be held in abeyance until such time.

**Formal Matters:**

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The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the elected claims are directed.

**Objections and Rejections under 35 U.S.C. 112:**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 14, 18 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because it is improper to recite "and" at the end of part (d). The correct format for Markush type of claim is to put "and" at the end of the part, which is the second from the last part, i.e., the word "and" should be placed at the end of part (e), instead of the end of part (d) in the instant claim. The claim is further indefinite for the recitation "complementary to a portion of ... SEQ ID NO:1 and having at least 20 nucleotides" in part (f) because it is unclear whether the nucleic acid sequence is complementary to at least 20 nucleotides, or it is at least 20 nucleotides long. Claim 14 is similarly indefinite.

The remaining claims are rejected for depending from an indefinite claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 3, 15 and 16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited in scope to a nucleic acid of SEQ ID NO:1, and a nucleic acid encoding a polypeptide of SEQ ID NO:2, does not reasonably provide enablement for claims to % variants of SEQ ID NO:1 (as claims 2 and 3), or a nucleic acid encoding % variants of SEQ ID NO:2 (as claims 15 and 16), which do not have a functional activity, or do not have the same functional activity as SEQ ID NO:2. The

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specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The claims are directed to % variants of SEQ ID NO:147, or a nucleic acid encoding a % variant of SEQ ID NO:2, which read on any or all variants meeting the sequence limitation, and encoding polypeptides either with or without a functional activity. The claims encompass an unreasonable number of nucleic acids encoding inoperative polypeptides. However, while the specification teaches that the polypeptide of SEQ ID NO:2 is a splicing variant of VEGF, it provides no guidance or working examples as to how the skilled artisan could use a nucleic acid encoding an inactive polypeptide variant of SEQ ID NO:2, as no functional limitation associated with the variants in the claims. Therefore, it would require undue experimentation to practice this invention as claimed, because the skilled artisan would have no reasonable expectation of being able to use the inactive variants for any purpose stated in the specification.

Due to the large quantity of experimentation necessary to determine how to use the nucleic acids encoding inoperative polypeptides, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the complex nature of the invention, and the breadth of the claims which embrace a broad class of structurally diverse variants, undue experimentation would be required of the skilled artisan to use the claimed invention in its full scope.

**Rejections Over Prior Art:**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-5, 14-16, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Keck et al., US 5,240,848.

Keck discloses a nucleic acid molecule comprising nucleotides 1-426 of SEQ ID NO:1 of the instant case with 99.5% sequence similarity, and encoding a human VPF (VEGF) polypeptide comprising amino acid sequence of SEQ ID NO:2 of the instant case with 100% sequence identity (see computer printout of the search results). The reference, therefore, anticipates claims 1-3 and 14. With respect to claims 15 and 16, as the prior art polypeptide comprises the sequence 100% identical to SEQ ID NO:2 of the instant case, the referenced nucleic acid anticipates the nucleic acid molecule of claims 15 and 16 as being a nucleic acid encoding an amino acid sequence at least 80% identical to SEQ ID NO:2, even though the prior art nucleic acid encoding a polypeptide, which is longer than SEQ ID NO:2 of the instant case. Further, as the present polypeptide is a splicing variant encoded by the same gene of the prior art, the expression of the prior art nucleic acid could result in the same polypeptide as the present SEQ ID NO:2 when a proper host cell is used. Additionally, Keck teaches an expression vector comprising said nucleic acid, and a host cell thereof (column 5, lines 27-34), thus, anticipates claims 4, 5, 18 and 19.

**Conclusion:**

No claim is allowed.

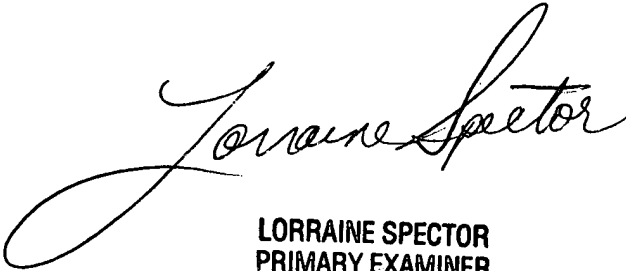
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**Advisory Information:**

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
LORRAINE SPECTOR  
PRIMARY EXAMINER

Dong Jiang, Ph.D.  
Patent Examiner  
AU1646  
12/18/02